# PSJ2 Exh 149

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# Purdue Pharma, LLP

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## Introduction and Background

On July 25, 2016, IMS Health US Compliance Solutions (formerly BuzzeoPDMA) entered into an agreement with Purdue Pharma (under attorney-client privilege with Skadden, Arps, Slate, Meagher and Flom) to conduct a Suspicious Order Monitoring (SOM) assessment of Purdue Pharma's (Purdue's) Order Management System. The purpose of the agreement was to leverage BuzzeoPDMA's Drug Enforcement Administration (DEA) and SOM knowledge to identify potential regulatory risks and provide potential recommendations to enhance Purdue's computer analysis system, SOM procedures and the firm's overall SOM compliance program. The review was intended to cover SOM concepts such as "knowing your customer," order management and review, reporting suspicious orders to the DEA and more. The overall goal was to highlight strict regulatory compliance requirements and best practices as found in the controlled substances pharmaceutical industry.

On August 4 and 5, 2016, an IMS Health team consisting of Paul Hamby, Group Director; Robert Williamson, Manager, DEA Consulting; and Michael Liu, Senior Manager, Advanced Analytics visited Purdue Pharma headquarters at the address noted above. IMS Health consultants were provided an opportunity to interview Purdue staff involved in various aspects of Purdue's current approach to SOM compliance. Deputy General Counsel Maria Barton opened the review and provided insight and focus during a brief meeting on the 4th. Giselle Issa, Director, OMS and Records Management, served as the audit "host" and provided relevant standard operating procedures and coordinated interviews and visits with Purdue staff. Additionally, Ms. Issa provided significant details of her role in Purdue's current SOM processes throughout the audit event. Purdue's staff were uniformly forthcoming and helpful.

Purdue Pharma LP is a privately held pharmaceutical company founded by two physicians more than 60 years ago. According to the firm's web site, the firm is engaged in the research, development, production and marketing of prescription and over the counter medicines and healthcare products, including pain medication and abuse deterrent technology.

Purdue became the subject of federal and state regulatory attention in around 2000. Drug abuse issues associated with Purdue's time release formulations of oxycodone (known as Oxycontin) surfaced in numerous areas, including most notably poor, rural communities. Purdue's products were also frequently mentioned in the media. In response, Purdue enhanced their corporate drug abuse prevention efforts. New staff was hired. The firm became active in the National Association of Drug Diversion Investigators and funded a program to provide intelligence on drug thefts. In around 2001, Purdue purchased IMS data for their sales staff to use in evaluating appropriate customers. Purdue also initiated a program to determine what pharmacies were purchasing their products from wholesalers.



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In subsequent years, Purdue developed a new drug abuse prevention formulation for their Oxycontin brand. The new formulation cannot be readily crushed and includes a gel like component. These two product qualities prevent the product from being injected. The success of the new product formulation has dramatically changed the drug abuse profile for Oxycontin. According to staff, Oxycontin now accounts for a very small percentage of the controlled substance market.

Purdue has approximately 825 employees, which are mostly located in Stamford, Connecticut, the corporate headquarters (700 of the total). The firm's manufacturing operations have been transferred to Wilson, North Carolina. The firm's controlled substance product line contains mostly Schedule II narcotics (Oxycontin, Ms Contin, Hysingla ER and Dilaudid). The firm also manufactures Butran, a Schedule III narcotic and one non-narcotic Schedule IV sedative (Intermezzio).

The report is organized around the BuzzeoPDMA approach to SOM. BuzzeoPDMA recommends that DEA registrants need a comprehensive approach to be successful in attending to the stated and implied DEA regulations regarding SOM. Each BuzzeoPDMA component of SOM Monitoring is addressed in the report along with a description of whether or not Purdue conforms to the recommended approach. Official "findings" are provided where deficiencies were discovered. Recommendations are included throughout as appropriate and there are descriptive "commentaries" which contain further BuzzeoPDMA opinion. A final section, "Conclusions and Recommendations" has been prepared with an aim to bringing the important considerations into focus.

## SOM Regulatory Foundation

The regulatory foundation for suspicious order monitoring is contained in the following regulation:

21 CFR §1301.74 Other security controls for **non-practitioners**; narcotic treatment programs and compounders for narcotic treatment programs.

> (a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.
>
> (b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. **Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency**.

Information contained in the regulations has been expanded by the DEA through communications furnished to registrants in 2006 and 2007. These "SOM letters" establish expectations for greater registrant customer oversight and reporting; however, neither the language of the regulation nor the DEA "SOM letters" provide a specific roadmap for DEA registrants to follow to be assured of compliance with the regulation. In correspondence to registrants dated 12.27.2007, the DEA states that "… the DEA does not approve or otherwise endorse any specific system for reporting suspicious orders."

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***BuzzeoPDMA recommends*** that clients develop their SOM systems to address each of the following elements:

- An order evaluation system that seeks to determine whether orders are of unusual size, of unusual frequency and/or deviate from a normal pattern.
- An aggressive "know your customer" program to be assured that controlled substance products are not being distributed to inappropriate customers or that the firm's products are not improperly distributed by others in their supply chain ("downstream distribution").
- Procedures to identify and "pend" orders that are possibly suspicious; investigate the "pended" orders, document the investigation of the orders, and report the orders to the DEA if required.
- Development of SOPs that describe the registrant's SOM program, processes and procedures
- A "culture of compliance" that recognizes the drug abuse potential of the products the registrant handles and supports employee actions as necessary for fulfilling SOM regulatory requirements.
- Management and staff regulatory training programs

The regulatory and legal complexities associated with "SOM Compliance" are exacerbated for manufacturers. The regulation clearly requires manufacturers (non-practitioners) to have an SOM system and the DEA has specifically alerted DEA registrants to this requirement. However, the DEA is also intimating that manufacturers have a secondary SOM system to know what their customers do with the products the manufacturers sell to them.

This is referred to as "downstream distribution" and/or "know your customers' customers." Although this is not required in the regulations and has not been mentioned in official correspondence from the DEA and/or published on the DEA's official web site, it is frequently characterized as a DEA expectation by DEA officials in public and private forums.

***BuzzeoPDMA recommends*** that manufacturer clients develop minimally at least a limited **secondary** SOM system to identify suspicious orders/activities with their product(s) which can be associated with their customers' customers.

## Overview of Purdue's SOM Program

Purdue's SOM energies appear to be blended between their **primary** SOM system (the processes and systems around SOM compliance for their immediate customers, e.g., wholesalers) and their **secondary** SOM system (the processes and systems around SOM compliance for their customers' customers, e.g., pharmacies). In fact, Purdue's current efforts appear to be more significant for their customers' customers than Purdue's direct customers. Although the firm's Standard Operating Procedures (SOPs)

will be addressed in more detail later, there are four SOPs that appear to address SOM. One SOP is titled "Controlled Substance II Order Process" and a second one is titled "Order Processing – OTC, Controlled III-V and Non-Controlled Prescription Products." These two SOPs are very similar. There is also an SOP titled, "System to Disclose Suspicious Orders of Controlled Substances." It is dated 3.12.2003; however it appears, in large part, to still be relevant. These procedures describe Purdue's **primary** SOM system.

A fourth procedure, titled "Order Management System" describes Purdue's Order Management System (OMS). This SOP is dated February 29, 2016. This SOP provides for "assessments of selected accounts" including distributor customers and "some of their retail customers." The procedure is characterized as an effort to assist Purdue customer's to "know their customers." Although SOM issues resulting from wholesaler misconduct are addressed to some degree in the SOP, the SOP appears more forcefully directed at "downstream distribution." This is considered a **secondary** SOM system.

For the purposes of reporting information, including Findings and Recommendations, information will be organized around the two SOM Concepts: 1) Purdue's **primary** SOM system which is a regulatory requirement for all "non-practitioners," including manufacturers will be referred to as their "primary SOM system" and 2) Purdue's **secondary** SOM system which is used to identify issues associated with "downstream distribution" will be referred to as their "secondary SOM system."

## Electronic Analysis of Orders

### Primary SOM System

Orders for controlled substances are mostly received electronically and in greatest quantity from Cardinal, McKesson and Amerisource Bergen. Although there is a significant number of smaller wholesale accounts (approximately 18 additional), they account for a relatively small percentage of Purdue's controlled substance business. Orders are electronically reviewed for credit worthiness and further reviewed by customer service representatives (primarily for technical requirements such as Form 222 and CSOS, although a low level of SOM review is performed). Three specialized credit representatives focus on the "big 3" and Schedule II controlled substances. Other representatives review the remaining accounts. The customer service team will also on occasion convert a manual order to an electronic order. For clarity, the term "electronic order" will mean an order for fulfillment in SAP, unless otherwise stated.

The processing and analysis of electronic orders is accomplished with the use of a computer software program known as ValueTrak. ValueTrak can be characterized as a relatively generic inventory management/forecasting program which allows for some customization. It has been developed by ValueCentric. As described during the site review ValueTrak will generally hold, stop or "pend" an order if the order is either 33% or 50% over the average using 24/16/12 weeks order units. (Different products have different rules.) If any line is held, the entire order is held. No additional order evaluation processes are conducted. The 33% and 50% "thresholds" as well as the 24/16/12 week periods were described as

being established based on "user experience" to a manageable level to work through the number of items that would "pend" instead of these measures being set via formal analytics or statistics (i.e. arbitrary threshold establishment).

Beside the threshold limit on order volume, no restriction is set up currently to track order frequency change and any significant deviation from normal patterns or trending. These are two specific factors identified in the regulatory definition of a suspicious order. The system does not provide summary statistics such as monthly pending statistics and/or a pending history for any specific customer. Although staff reported that some enhancements could be made to the current ValueTrak approach, it was not clear that all the regulatory necessary improvements could be made within the solution even with support from ValueCentric. (See below for more on ValueTrak observations.)

Consultants learned during their visit that Purdue in Wilson does manufacturing and distribution activities for Rhodes, a firm that handles generics. Although there is an association between Purdue and Rhodes, Purdue staff characterized the relationship as very separate and distinct. Rhodes is currently specializing in mostly generic products. Although Rhodes' products are in ValueTrak, there does not appear to be distinct SOM order review / analysis.

Consultants learned after the onsite visit that other sales managers were responsible for Rhodes' products. Although there is no electronic analysis of orders, staff does perform manual calculations and has developed some internal systems to look for suspicious orders. Accounts are sorted by class of trade, six month rolling averages are developed to normalize patterns and develop trends. Monthly sales reports are also examined and the sales staff is consulted weekly.

Rhodes does not conduct any "downstream distribution" activity.

Technical Assessment of Purdue's OMS ValueTrak System

Purdue's electronic order monitoring system for its customers is a threshold value based solution built on the ValueTrak software. There is no statistical modeling based solution to consistently track quantity/volume, frequency and trend.

1. ValueTrak is a generic software program not developed specifically to meet DEA regulatory requirements.
2. Threshold values set by Purdue using 33% or 50% above the mean are biased to penalize all small wholesalers. For example, a wholesaler changes to order four units OxyContin from ordering two units before could be pended because this is 100% above the average. However, from a business perspective, this could be acceptable.
3. Threshold values set by Purdue using 33% or 50% above the mean may not fit when there is significant volume change as a result of competition or product promotion such as pricing changes.

4. Threshold values set by Purdue using 33% or 50% above the mean are arbitrary in nature vs. established based on advanced mathematics, statistics or similar techniques.
5. The threshold values use the same rule for all wholesalers, which is not appropriate given Purdue's disparate customer base.
6. Threshold values set-up at the NDC level may not be able to capture the activities, if any, of switching from one NDC to another; however, both NDCs could contain the same controlled substance.
7. Using 24/16/12 weeks order history to calculate averages may not provide Purdue with the ability to track the deviation from normal ordering trends.
8. Purdue may not have the in-house expertise or experience to develop a statistical modeling solution for a more defensible suspicious order monitoring system.

***Findings and Recommendations***

**Findings**

1. Purdue's order entry system does not measure frequency and trend/pattern, two of the three elements contain in the DEA's definition of a "suspicious order."

2. Size threshold values set by Purdue are arbitrary in nature vs. established based on advanced mathematics, statistics or similar techniques.

3. Purdue's order entry system does not include orders for Rhodes' customers and the analysis of Rhodes' customer orders is manual and may be considered arbitrary.

***BuzzeoPDMA recommends*** that Purdue immediately incorporate additional information regarding Rhodes' customer orders. If possible, these orders could be evaluated in ValueTrak, either in combination with the Purdue orders or as a separate internal system. (Internal distinctions are of no consequence under the DEA's regulations. All orders are simply considered orders.)

***BuzzeoPDMA recommends*** that Purdue seek to either customize ValueTrak (which appears difficult as ValueTrak was not built to comply with the SOM size, pattern, and frequency requirements) or pursue a "bolt on" SOM solution to work in conjunction with ValueTrak which will properly scrutinize orders so that the order entry system is, at a minimum, consistent with the regulations.

***BuzzeoPDMA recommends*** that the SOM system undergo a formal validation.

***Commentary:*** *As noted in the technical assessment, the current ValueTrak formulas may have little utility in defending the suitability of the formulas to DEA. The regulation is vague and the DEA has not provided guidance that is definitive. In this environment, DEA registrants and BuzzeoPDMA clients are placed in the position of having "defensible" systems that can be explained in light of the specific information contained in the regulation and the spirit of what the law intends to do. The ValueTrak formulas can be characterized as arbitrary and difficult to defend.*

**Secondary SOM System**

The secondary SOM system has been developed with the support of IMS Health data and other data sources available to Purdue. This data provides information regarding pharmacy purchases of Purdue products. The firm has a business agreements with certain customers which is described as a Fee for Service program. Purdue pays their customers who distribute their product provided that they provide information on who they ship to. Staff reported that not all of their wholesale customers participate in the Fee for Service program. The current approach goes directly to the issue of "know your customers' customer."

According to staff, the current efforts in this area are approximately 8 or 9 years in the making. Sales information contained in an Oracle database caught the attention of staff originally. In response to the initial data, Purdue's IT staff began to analyze the information using the mathematical formula of two standard deviations above the mean along with some other items, such as orders per day, ordering from different wholesalers etc. New measures were introduced through the years – state and national averages and buying behaviors regarding 40, 60 and 80 milligram purchases. The system that evolved over time consisted of using formulas in an "excel" spread sheet which could be manipulated by sorting and tweaking to reach conclusions about whether certain pharmacies were purchasing suspicious quantities. These pharmacies were selected for further investigation. External diversion information was also used to stimulate investigation into pharmacy purchases. For example, it was explained that the orders from Tennessee pharmacies were a concern at one point, based upon external diversion information.

Although the data did not always provide relevant information and, as noted, the *calculations* were changed over time, the secondary model ***did*** appear to provide some valuable insight.[1] Purdue used the information to conduct what appeared to be relevant inquiries and investigations. In some cases the information was reported to the DEA and in other instances it was reported to the distributors.

***Commentary:*** *BuzzeoPDMA feels that there is no significant electronic model for the secondary system. In terms of what a true SOM electronic model would have, the orders would be in real time, the calculations would be more systematic and results would be more uniform.*

*BuzzeoPDMA postulates that the real issue for the secondary model is the time expended on it. According to staff the number of pharmacies that appear to require further investigation are in decline and that seems to be stimulating an interest in new formulas and/or more tweaking. According to Purdue*

[1] According to Wikipedia, "in mathematics and computer science, an algorithm is a self-contained step-by-step set of operations to be performed. Algorithms exist that perform calculation, data processing and automated reasoning." As used in this report, the word algorithm will only be used to describe a **series of calculations that are performed together in a step-by-step process** with a goal that may provide a level of automated reasoning that can assist in making decisions.

*management, the new formulation is an effective deterrent to diversion. It was reported that Purdue now represents a very small segment of the overall controlled substance prescription market.*

***BuzzeoPDMA recommends*** that Purdue seek to develop better targeting procedures for its "customers' customers" program with an aim to reducing the number of pharmacies investigated and the time staff spends reviewing spread sheets and conducting investigations. Operational efficiency improvements via additional automation and/or statistical evaluations are advisable to reduce the current highly labor intensive approach

## Purdue's "Know Your Customer" Procedures

**Primary and Secondary SOM Systems**

In general Purdue appears to maintain close business and working relationships with the majority of their customers. These ongoing relationships touch upon numerous controlled substance activities including SOM. According to staff, Purdue will meet with their customers on a routine basis ("every year or two"). They also have quarterly telephone calls. Representatives from legal and/or security go onsite periodically to at least some of their customer accounts. Neither Sales nor Marketing are involved in the visits described to consultants; however, other separate visits no doubt occur with these groups.

Information developed during site visits and/or during telephone calls is documented in various work products (e.g. email, Microsoft Word document attachments, etc.); however, no corporate file/repository for "DEA Know Your Customer" reports was identified. Additionally, it was reported by Purdue staff that customer visits and quarterly calls have not occurred for smaller customers (10 smallest) which is still required as a part of a complete "due diligence" program.

It was explained that Rhodes' customers, are also involved with similar reviews. It appeared from interviews with staff that sales support is used to set up the vendor accounts (80% of the business is with the "Big Three"). Although there is no ongoing due diligence, the SOM lead for Rhodes indicated that she communicates with the sales team multiple times daily and that there is a weekly meeting where all relevant information is shared. No real ongoing due diligence activities were noted.

It was reported that Purdue employees may discuss possible issues with pharmacies who are purchasing Purdue controlled substances from the wholesalers. In at least one instance consultants noted that SOM representatives from their wholesalers shared information and it appeared that the two component staff members worked on a common pharmacy. Information gleaned from the site visits is discussed during Order Management System (OMS) committee meetings which are conducted on a quarterly basis.

The OMS Committee consists of higher level employees from sales, marketing, credit etc. Legal appears to drive the agenda. Although the main purpose of the committee appears to be to review information developed by staff regarding the downstream distribution of Purdue products to pharmacies for the

purpose of possibly reporting the pharmacies to the DEA, in practice, the committee appears to discuss controlled substance activities affecting Purdue more generically, which includes ongoing liaison with Purdue wholesaler customers.

***Findings and Recommendations***

**Findings**

1. Purdue does not perform "due diligence" for all of their customers as a part of their know your customer program.

***BuzzeoPDMA recommends*** that Purdue formalize their SOM Know Your Customer program. Also, Rhodes' activities should be incorporated into the larger program. As noted, it is essential that Purdue include due diligence for *all* their customers. SOM risk is more likely to exist with smaller wholesalers.

Procedures for vetting customers differ throughout the regulated industry; however, BuzzeoPDMA recommends that Purdue seek to determine whether their customers have adequate SOM procedures in place. Questionnaires are commonly used; however, interviews are also acceptable and preferable. All customers should be exposed to the same set of questions. Interview questions should be "open ended" and the results of the interview should be documented in Purdue's official files.

Customer responsiveness to Purdue's due diligence activities may differ from customer to customer. Some customer's may offer to supply Purdue with SOPs, while some may not. *If Purdue cannot conclude that the customer has adequate safeguards in place to handle their product responsively, the firm should not approve them as a customer.*

## Pending, Investigating and Acting on Orders

**Primary SOM System**

Consultants learned during a series of interviews with staff that "credit" and "customer service" play a prominent role in setting up accounts and that orders can be "pended" automatically if the customer's credit limit is violated. These procedures are primarily related to financial issues; however, the customer service department performs an initial review of the order for SOM types of anomalies. This is also consistent with the firm's SOPs. However, the deeper analysis of potentially "unusual" orders occurs after order information is entered into the ValueTrak software program described above.

Consultants felt that "Strategy and Marketing" "owned ValueTrak. Although legal staff would frequently discuss being consulted and having a role to play in researching problematic orders/accounts the final decisions appeared to primarily rest with the sales department. From a business standpoint, this might make sense since the Director of Strategy and Marketing also manages the software; however, from a

regulatory standpoint, it is problematic. The process for investigating procedures was described as reviewing available information in ValueTrak regarding the customer's ordering habits and inventory levels. It was reported that in many instances a review of the data may in and of itself be sufficient to "clear" the order. The ValueTrak software system contains a "dashboard" and many intuitive features. If the data itself was not sufficient, the Director of Marketing may call the customer or make inquiries with the OMS lead and/or customer service.

Consultants asked whether there was ever any pressure to facilitate orders by the firm's sales leadership and/or other Purdue organizational units. The Director of Marketing proffered that a predecessor employee may have been affected by other organizational goals; however, he was not. If there was pressure, the order would be reduced or other order elements would be allowed to go to shipment. According to staff, this might have happened a couple of times a year. It appeared that a significant portion of the final decision as to whether to ship or not ship and report the order to the DEA rests with the Director of Marketing. ValueTrak does provide an area for documentation but staff indicated that the comment field may not always be completed for "more routine" clearing of orders that have pended.

A full description of the use of ValueTrak and the investigation of pended orders is not contained in any of the SOPs provided to staff.

As previously noted, Rhodes' orders are evaluated manually. According to staff, no order has ever been reported to the DEA. Also, as previously noted, Rhodes does not do any SOM activity relating to "downstream distribution."

**Secondary SOM system**

There is no real time "pending" of orders involved with Purdue's Order Management System, which is based upon historical data (e.g., when potentially problematic pharmacies are identified). Still, the purchase information is mathematically analyzed and problematic accounts are identified for review. In this case the OMS lead is solely responsible for identifying the suspicious accounts. However, acting upon the information developed during the reviews appears to mostly be accomplished by the OMS committee.

***Findings and Recommendations***

**Findings**

1. Purdue's SOM procedures in practice deviate from their official published SOM procedures.
2. Orders that are investigated and cleared are not uniformly or consistently documented.

***BuzzeoPDMA recommends*** that Purdue include Rhodes' orders along with their other ongoing controlled substance order review.

***BuzzeoPDMA recommends*** that the review of pended orders be accomplished by an entity that does not have marketing or sales as their core mission.

***BuzzeoPDMA recommends*** that Purdue develop a unified SOM program with a centralized organizational structure and SOPs to include more consistent control of the order release process.

## Purdue's SOM SOPs

**Primary SOM System**

An un-numbered SOP entitled "New Account Application Processing" was provided. This describes opening new accounts, primarily based upon credit. The SOP provides limited SOM guidance, if any.

SOP 7.19 entitled, "Order Processing - OTC, Controlled III-V and Non-Controlled Prescription Products" and SOP 7.8 entitled "Controlled Substance Schedule II Order Process" form the operational basis for SOM order entry management. They are both current (revised in June of 2016). In addition to SOM policy concerns, there are instructions relating to expired DEA registration numbers, use of Form 222 and other operational details such as making manual entries into SAP, the use of "Customer Build Forms" and more.

SOM concerns described in general terms such "extremely large," or "potentially suspicious" are visibly noted in both SOPs; however, the SOPs for ordering Schedule II controlled substances appear to mostly address regulatory operational details. Other SOM language is more plentiful in the "Controlled III-V" SOP. Review and escalation procedures are identified to begin with customer service and escalate through credit, sales, marketing and ultimately to the VP, Associate General Counsel "… who will determine if additional investigative steps are required and if the findings should be reported to the Field Office of the DEA." Additional SOM detail is provided later in the SOP where the "fee for service" delivery block is described based upon customer inventory levels. This is where the ValueTrak system is mentioned. According to the SOP, "written sales approval is required in order to remove the delivery block for shipping."

A Finance and Accounting SOP entitled "System to Disclose Suspicious Orders of Controlled Substances" was also provided. This SOP was dated 3/12/2003. It is similar to the others, placing a large emphasis on credit worthiness. The Associate General Counsel and the Credit Department will make a report to a number of other officials regarding any potential suspicious order and the CEO will be notified. Reporting orders to the DEA are not described.

**Secondary SOM System**

GC SOP 0007.1, entitled, "Order Management System" describes Purdue's efforts to "know their customers' customers." The procedure is dated 2.29.2016 and generally describes the Order Monitoring System as it was described during Consultant interviews with staff. Although the fee for service system is noted in the SOP, it is simply one of multiple sources of information that may stimulate an investigation into a pharmacy's possible illegal or improper use of Purdue controlled substances. Although the SOP

provides for the reporting of pharmacies to the DEA, it does not identify who exactly is supposed to report the order to the DEA. Instead, "It is recommended that the same person conduct the investigation, decide (in consultation with one or more colleagues or managers) whether or not to cancel the order, and also provide the report to the DEA."

According to staff, there had been an SOP for Rhodes' SOM system; however, it was retired. Staff related that there was a work instruction which included some information regarding SOM concerns.

***Commentary:*** *From an SOM perspective, the SOPs are disjointed, which is noted as a common theme in Purdue's SOM program. In some cases the SOPs are in the passive voice and in all cases, responsibility for opening accounts, reviewing orders, pending orders, and clearing/reporting orders is not adequately developed into a single corporate SOM policy.*

**Finding and Recommendation**

1. Although the secondary SOP indicates that Purdue will determine whether a state SOP program is in place, it did not appear that Purdue was actively involved in such activities.

***BuzzeoPDMA recommends*** that Purdue conduct a search of each state's legal requirements for SOM and implement SOM procedures as required as a part of the firm's overall SOM program.

***BuzzeoPDMA recommends*** as a best practice:

- That Sales, Customer Relations and Marketing have a perfunctory role in all SOM activities.
- That order entry analysis procedures be fully described to address quantity, frequency and pattern as these are directly mentioned in the regulatory definition of a suspicious order.
- That SOPs be established to include Rhodes' products.
- That responsibilities relating to evaluating, investigating, clearing orders or reporting customers to the DEA be assigned to a position whose main responsibilities are related to corporate compliance.

## Purdue's SOM Support and Culture of Compliance

Purdue has developed numerous programs and initiatives to reduce the abuse of their controlled substance products. For example, the firm developed the voluntary RX Patrol program for affected pharmacies and security personnel to share pharmacy theft intelligence. The firm is also an active member of the National Association of Drug Diversion Investigators. The firm has invested time and money in following up on pharmacy purchases and conducting investigations for making reports to the DEA and or their wholesalers. Additionally, the firm has conducted research to change their product formulations which have perhaps been the biggest factor in reducing the diversion and abuse of their products.

However, Consultants noted a lack of training on SOM items.

## Conclusions and Recommendations

At a high level BuzzeoPDMA found that the firm's SOM activities are at times poorly organized, fragmented and difficult to understand. Also, as noted throughout, sales, marketing, customer service and other similar programs should have a minor role in SOM management. SOM programs are frequently found in corporate compliance, quality control and/or standalone DEA compliance programs. BuzzeoPDMA consultants learned from the outset that Purdue's legal department had the lead in SOM management, perhaps as a legacy from the times when Purdue was the subject of legal actions and concerns. Consultants requested an interview with corporate compliance and learned that the firm's compliance department is positioned to be separate from sales and to have access to high levels in the firm. Consultants also noted that there is a "controlled substance team"; however, they concluded that this team is better suited for law enforcement liaison activities and security oversight. Consultants noted good infrastructure and depth of understanding in legal, and an ability to make independent SOM decisions.

BuzzeoPDMA consultants recommend that Purdue modernize, streamline, and ensure a complete approach to SOM. Although the firm's legal department has some staff and expertise to handle aspects of SOM, it is an uncommon approach to SOM for full responsibility to reside in a legal department. It is recommended that SOM be assigned to Purdue's compliance department if organizational appropriate and prudent. As noted above, this organizational unit is typically well positioned for independence and access to higher level staff, two extremely important components of a "best practice" SOM system.

As the new organization is developed and implemented, **all** SOM activities for the company should be under the general direction and control of the new SOM unit. Although it would be permissible and make sense to have customer service initially qualify new customers for possible SOM issues, the final decisions about who to ship to, whether a wholesaler is problematic or whether a customer's customer should be reported to the DEA should fall to the SOM unit.

In building a new SOM program, BuzzeoPDMA recommends that Purdue adhere to the following strategy.

1. Review the use of the ValueTrak system in overall SOM compliance and supplement or replace ValueTrak's SOM verification efforts with more defensible software / statistics.
2. Develop a "know your customer" program for direct Purdue customers with standard site visits, recurring updates and internal standardized files.
3. Revisit the "know your customers' customers program to determine what level of support is meaningful and efficient.
4. Re-evaluate the use of the OMS formulas with an aim to develop better efficiency and less staff time for customers' customer verifications

5. Modify and develop new Standard Operating Procedures to place ultimate responsibility for approving accounts and evaluating orders in the Compliance Department. Ensure all SOM responsibilities are covered.
6. Develop and provide training on Suspicious Order Monitoring for both corporate and field operations.
7. Partner with a subject matter expert, if required, to jumpstart the above activities and to ensure all activities are implemented as efficiently and regulatory compliant as possible. This would appear to include subject matter expertise consulting, training, and activity implementation assistance.

## QUALIFICATIONS

1. The foregoing analysis reflects our observations and recommendations based on information and individuals made available to us by the company during the review period. A review of additional records and interviews with additional representatives would likely result in additional issues and recommendations.

2. The foregoing recommendations represent our best professional judgment based on our knowledge of the Controlled Substances Act (CSA), the implementing regulations, and our experience with them. Many of the requirements of the CSA and regulations thereunder are subject to interpretation and are subjective. Implementation of these recommendations does not guarantee that the Drug Enforcement Administration (DEA) would not find any violations; the recommendations must be considered with this in mind.

3. No analysis has been provided as to the consequences of current or prior violations of the CSA and the implementing regulations.